

Remarks

Claims 1-33 are canceled. A new claim drawn to the elected species, Claim 34, has been added. This should care for the Examiner's objection to Claims 1, 6, 8, 15 and 33 as containing non-elected subject matter. Basis for this amendment can be found at least in Example 30 of the specification. Applicants respectfully request entry of the amendments under 37 CFR 1.116(b) as complying with the Examiner's objection, and allowance of Claim 34 in view of the remarks below.

Election/Restrictions

Applicants assert that in view of the further amendments to the claims and remarks below, the species of Example 30 as claimed in Claim 34 is appropriately allowed, and thus respectfully request rejoinder of the non-elected subject matter of Claims 1, 6, 8, 15 and 33.

Claim Rejections: 35 USC 103(a)

In the Official Action date April 11, 2008, the Examiner has maintained the rejection of Claims 1, 6, 8, 15 and 33 as obvious under 35 USC 103(a) in view of Cheshire *et al.* Applicants respectfully submit that neither the instant claim nor the elected species of Example 30 are obvious in view of this reference.

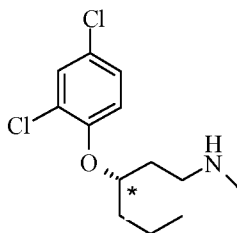
Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) describes the factual inquiries that are applicable in determining obviousness:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicants discuss each factor below as it relates to the instant application and the above stated reference.

1. Determining the scope and contents of the prior art.

On Page 11 of Official Action dated September 5, 2007, the Examiner states that Cheshire *et al.* teaches the compound of Example 30, (S)-[3-(2,4-dichloro-phenoxy)-hexyl]-methyl-amine, as seen in Figure A below:



(*S*)-[3-(2,4-dichloro-phenoxy)-hexyl]-methyl-amine

Figure A.

2. Ascertainment of the difference between the prior art and the claims

The Examiner has asserted that the difference between the prior art of Cheshire *et al.* and the instantly claimed compounds is that the compound of Cheshire *et al.* is a position isomer of the compound depicted in Example 30 of the instant application. Moreover, the Examiner cites Ex parte Henkel, 130 USPQ 474 and Ex parte Weston, 121 USPQ 429, for the notion that position isomers are generally of sufficiently close structural similarity that there is a presumed expectation that such compound will possess similar properties. However, applicants, respectfully disagree. Cheshire *et al.* describes the compound 3-(**2,5**-dichlorophenoxy)-N-methyl-1-hexamine, and other compounds, all which **require** a **5**-substituent on the phenyl moiety, whereas Example 30 describes a **2,4**-substituted phenoxypropylamine clearing lacking the **5**-substituent. Cheshire *et al.* also requires the compound 3-(2,5-dichlorophenoxy)-N-methyl-1-hexamine be a mixture of stereoisomers, whereas Example 30 is explicitly a single stereoisomer, the **S** stereoisomer, (**S**)-[3-(2,4-dichloro-phenoxy)-hexyl]-methyl-amine. Further in its teaching, Cheshire *et al.* presents 28 of 29 exemplified compounds as stereoisomeric mixtures and only one exemplified compound as a single stereoisomer, Example 29. Example 29 of Cheshire *et al.* is the **R** stereoisomer which is the **opposite** configuration to the elected species of the instant invention.

3. Lack of rationale and motivation for a Finding of Prima Facie Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The teaching or suggestion to make the claimed combination and the

reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Further, “*in addition to structural similarity* between the compounds, a prima facie case of obviousness also requires a showing of ‘adequate support in the prior art’ for the change in structure.” Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 83 USPQ2d 1169 at 1174 (Fed. Cir. 2007) (*citing In re Grabiak*, 769 F.2d 729, 731-32 (Fed. Cir. 1985) (emphasis added)). As such, “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound *in a particular manner* to establish prima facie obviousness of a new claimed compound.” *Id.* at 1174 (emphasis added). The United States Court of Appeals for the Federal Circuit has recently clarified that “in order to find a prima facie case of unpatentability in such instances, a showing that the ‘prior art would have suggested making the *specific* molecular modifications necessary to achieve the claimed invention’ [is] also required.” *Id.* at 1174 (internal citations omitted, emphasis added).

a. No teaching, or suggestion to make the 4-substituent of the elected species in view of Cheshire *et al.*

Applicants assert that there is no teaching or knowledge in the art to modify the required 5-substituent of the phenoxypropylamines of Cheshire *et al.* to arrive at the 4-substituted compound of Example 30. Any teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Nothing in the disclosure of Cheshire *et al.* indicates that the compound of Example 30 above is the most desirable starting point for modification to develop further compounds that have similar properties. *Takeda*, 83 USPQ2d at 1156. Furthermore, the Examiner has not pointed to any art which indicates the desirability of “ring-walking” a substituent from the 5 position as described in Cheshire *et al.* to the 4 position of the compound of Example 30. *Takeda*, 83 USPQ2d 1179. Lastly no art as been cited as demonstrating the interchangeability of 2,5-substituted phenoxypropylamines with 2,4-substituted phenoxypropylamines. Thus there is no motivation to alter the substitution pattern on the phenyl ring on the left side of the compounds disclosed in Cheshire *et al.* to arrive at the compound of Example 30.

b. No teaching, or suggestion to make the S isomer of the elected species claimed compounds in view of Cheshire *et al.*

Applicants assert that there is no teaching or knowledge in the art to modify 3-(2,5-dichlorophenoxy)-N-methyl-1-hexamine as a mixture of stereoisomers of Cheshire *et al.* to arrive at the S stereoisomer of the elected species. Any teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Nothing in the disclosure of Cheshire *et al.* indicates that the S stereoisomer of Example 30 above is the most desirable starting point for modification to develop further compounds that have similar properties. *Takeda*, 83 USPQ2d at 1156. Applicants further assert that in exemplifying a single isomer, the R stereoisomer, Cheshire *et al.* teaches away from the S stereoisomer of the elected species above as the most desirable starting point for modification to develop further compounds that have similar properties. The Examiner has pointed to no art demonstrating the motivation to modify the stereoisomeric mixtures of Cheshire *et al.* to arrive at the S stereoisomer of the present invention. Thus there is no motivation to alter the stereoisomeric mixtures of the modify 3-(2,5-dichlorophenoxy)-N-methyl-1-hexamine compounds disclosed in Cheshire *et al.* to arrive at the S stereoisomer compound of the present invention.

In the Official Action date April 11, 2008, the Examiner has maintained the rejection of Claims 1, 6, 8, 15 and 33 as obvious under 35 USC 103(a) in view of Cheshire *et al.* The Examiner points the applicants to MPEP 2141 in particular subsection (E) "Obvious to Try" as most relevant to the instant ground of rejection. The applicants respectively disagree that the elected species of Example 30 would be obvious to try in view of Cheshire *et al.* Applicants direct the Examiner to additional passages in MPEP 2141 "(E)"Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;". Applicants assert the possible number of structural modifications to 3-(2,5-dichlorophenoxy)-N-methyl-1-hexamine of Cheshire *et al.* is infinite and that a solution would not be predicted with a reasonable expectation of success. Thus, the elected species of Example 30 would not be obvious to try in view of 3-(2,5-dichlorophenoxy)-N-methyl-1-hexamine of Cheshire *et al.*

In view of the above arguments, Applicants assert that the instantly claimed compounds are not obvious in view of Cheshire *et al.* under 35 U.S.C §103(a). Applicants respectfully request allowance of Claim 34.

Applicants respectfully request entry of the amendments to the claims described above and that the Examiner find the species of Example 30 allowable. The Examiner is invited to contact the undersigned agent should any questions arise as a result of the submission provided herein, or in the event any questions arise at any point during examination.

Respectfully submitted,

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July 11, 2008